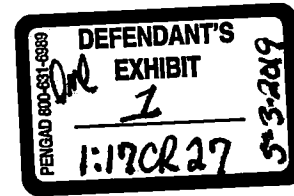


IN THIS SECTION



FDA Drug Safety Communication: FDA warns about serious risks and death when combining opioid pain or cough medicines with benzodiazepines; requires its strongest warning

The FDA has issued new information about the combined use of medication-assisted treatment (MAT) drugs with benzodiazepines or other central nervous system depressants. See the FDA Drug Safety Communication (/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-urges-caution-about-withholding-opioid-addiction-medications) issued on 9-20-2017.

Safety Announcement

[8-31-2016] A U.S. Food and Drug Administration (FDA) review has found that the growing combined use of opioid medicines with benzodiazepines or other drugs that depress the central nervous system (CNS) has resulted in serious side effects, including slowed or difficult breathing and deaths. Opioids are used to treat pain and cough; benzodiazepines are used to treat anxiety, insomnia, and seizures. In an effort to decrease the use of opioids and benzodiazepines, or opioids and other CNS depressants, together, we are adding *Boxed Warnings*, our strongest warnings, to the drug labeling of prescription opioid pain and prescription opioid cough medicines, and benzodiazepines.

Health care professionals should limit prescribing opioid pain medicines with benzodiazepines or other CNS depressants only to patients for whom alternative treatment options are inadequate. If these medicines are prescribed together, limit the dosages and duration of each drug to the minimum possible while achieving the desired clinical effect. Warn patients and caregivers about the risks of slowed or difficult breathing and/or sedation, and the associated signs and symptoms. Avoid prescribing prescription opioid cough medicines for patients taking benzodiazepines or other CNS depressants, including alcohol.

Patients taking opioids with benzodiazepines, other CNS depressant medicines, or alcohol, and caregivers of these patients, should seek medical attention immediately if they or someone they are caring for experiences symptoms of unusual dizziness or lightheadedness, extreme sleepiness, slowed or difficult breathing, or unresponsiveness. Unresponsiveness

means that the person doesn't answer or react normally or you can't wake them up. Talk with your health care professional if you have questions or concerns about taking opioids or benzodiazepines (see List of Prescription Opioid Pain and Cough Medicines, and List of Benzodiazepines and Other CNS Depressants).

Opioids (/drugs/information-drug-class/opioid-medications) are a class of powerful narcotic medicines that are used to treat pain severe enough to warrant use of an opioid when other pain medicines cannot be taken or are not able to provide enough pain relief. They also have serious risks including misuse and abuse, addiction, overdose, and death. Opioids such as codeine and hydrocodone are also approved in combination with other medicines to reduce coughing. Benzodiazepines are a class of medicines that are widely used to treat conditions including anxiety, insomnia, and seizures.

We conducted and reviewed several studies showing that serious risks are associated with the combined use of opioids and benzodiazepines, other drugs that depress the CNS, or alcohol (see Data Summary).¹⁻⁶ Based on these data, we are requiring several changes to reflect these risks in the opioid and benzodiazepine labeling, and new or revised patient Medication Guides (/drugs/drug-safety-and-availability/medication-guides). These changes include the new Boxed Warnings and revisions to the *Warnings and Precautions*, *Drug Interactions*, and *Patient Counseling Information* sections of the labeling.

We are continuing to evaluate the evidence regarding combined use of benzodiazepines or other CNS depressants with medication-assisted therapy (MAT) drugs used to treat opioid addiction and dependence. We are also evaluating whether labeling changes are needed for other CNS depressants, and will update the public when more information is available.

We urge patients and health care professionals to report side effects involving opioids, benzodiazepines, or other medicines to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

List of Prescription Opioid Pain and Cough Medicines



List of Benzodiazepines and Other CNS Depressants*



Facts about Opioids and Benzodiazepines



Additional Information for Patients



Additional Information for Health Care Professionals



Data Summary



References



en Español (/drugs/drug-safety-and-availability/la-fda-advierte-acerca-de-los-graves-riesgos-y-muerte-cuando-se-combinan-medicamentos-opioides-para)

Drug Safety Communication (/media/99761/download) (PDF - 74KB)

Related Information

- Opioid Medications (/drugs/information-drug-class/opioid-medications)
- The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective (/drugs/information-consumers-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective)
- Think It Through: Managing the Benefits and Risks of Medicines (/drugs/information-consumers-drugs/think-it-through-managing-benefits-and-risks-medicines)